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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/618,194 | 07/11/2003 | Eva M. Sevick-Muraca | 017575.0700 | 4277 |
| 5073 | 7590 | 04/03/2008 | EXAMINER | |
| BAKER BOTTS L.L.P. | | | WAQAS, MUHAMMAD | |
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| DALLAS, TX 75201-2980 | | | | |
| | | | ART UNIT | PAPER NUMBER |
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| | | | 04/03/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/618,194 | Applicant(s) SEVICK-MURACA ET AL. | |
| | Examiner MUHAMMAD WAQAS | Art Unit 4153 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/28/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/04/2005, 11/24/2004 and 12/17/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 12/17/2003 and 11/24/2004 have been received and made of record.

Priority

2. Receipt is acknowledged of paper filed under 35 U.S.C 119 (e), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3-13, 15, 17-18, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance (US Patent No. 5, 673, 701) in view of Benaron et al. (US Patent No. 5, 987, 346).

Chance discloses an optical system for the examination of biological tissue. The system comprises a laser diode (col.7, lines 30-55) that direct time-varying excitation light into the tissue of a body (col. 2, lines 16-21). The time-varying excitation light consists of a spherical wave (col. 14, lines 19-24). An optical band pass filter (col. 12, lines 28-36) is used to reject the re-emitted light (col. 9, lines 9-14). Chance further discloses a fluorescent contrast agent that is injected into the target tissue (col. 19, lines 30-34) to obtain information for the imaging apparatus to image the target tissue (col. 4, lines 27-36). A processor is used to establish value corresponds to the level of the fluorescence characteristic at different positions (col. 5, line 57 - col. 8, line 34).

However, Chance fails to disclose using light wavelength between 700 nm and 900 nm and to direct the light on lymph node for imaging lymph node.

Benaron discloses a device that uses different wavelength of light to classify different types of tissue depending upon the emitted light characteristics. A pulsed light (col. 4, lines 44-46) with wavelength between 700 nm and 900 nm (col. 4, lines 31-35) is used for the detection of lymph nodes (col. 4, lines 14-31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chance's optical system and use light with larger range of

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wavelength between 700 nm and 900 nm as disclose by Benaron for obtaining images of variety of tissues.

4. Claims 2 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance as modified by Benaron (hereinafter combination 1) as applied to claims 1, 3-13, 15, 17-18, 21-23 above, and further in view of Hochman et al. (US Patent No. 5, 699, 798).

Combination 1 discloses the invention described above. However combination 1 fails to disclose using contrast agent that comprises indocyanine green.

Hochman discloses a method for optically imaging tumor tissue. An indocyanine green contrast agent is used that absorbs light in the range of 730 nm to 840 nm (col. 3, lines 54-56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify combination 1 and use indocyanine green contrast agent as taught by Hochman for obtaining better and clear images.

5. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance as modified by Benaron (hereinafter combination 1) as applied to claims 1, 3-13, 15, 17-18, 21-23 above, and further in view of Tsuchiya et al. (US Patent No. 5, 441, 054).

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Combination 1 discloses the invention described above. However combination 1 fails to disclose determination of the light scattering value using a mathematical relationship.

Tsuchiya discloses an apparatus for measuring light absorbance in scattering medium. light characteristic in the scattered medium is determined by obtaining various kinds of information including integration value of the absorbance coefficient (abstract) and a mathematical relationship is used corresponds to the diffusion approximation of the scattered light (col. 11, lines 5-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify combination 1 and use mathematical relationship to obtain light information in scatter medium as taught by Tsuchiya for better approximation of the scatter medium to obtain optimal diagnostic results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Muhammad Waqas whose telephone number is (571)270-3817. The examiner can normally be reached on Mon-Thurs. 8:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MW
/M. W./
Examiner, Art Unit 4153
03/26/08

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4153